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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,796	06/20/2000	Yasir Skciky	014058-009050US	6269

20350 7590 08/25/2004

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EXAMINER

SWARTZ, RODNEY P

ART UNIT PAPER NUMBER

1645

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/597,796

Applicant(s)

SKEIKY ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 55-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 55-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2-26-01.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

1. Applicants' Response to Restriction, received 5July2001, is acknowledged. Applicants elect, with traverse, Invention I, claims 1-15, drawn to protein composition, classified in class 424, subclass 248.1. Applicant's traversal is on the grounds that all four inventions stem from a common concept and theory and therefore prosecution of all four inventions would not place a substantially greater burden on the examiner. This is not found persuasive because the inventions have acquired a separate status in the art as shown by their different classification, and while the searches may overlap, the searches are not coextensive. The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, 3, 5, 6, and 9 have been amended. New claims 55-62 have been added. Claims 16-54 have been cancelled.

2. Applicants' Amendment, received 17December2001, is acknowledged. Claims 1-3,5, 6, 9, 55, and 62 have been amended. New Claims 63 and 64 have been added.

3. Claims 1-15 and 55-64 are pending and under consideration.

### **Drawings**

4. Informal drawings were filed with the application. Formal drawings will be required prior to allowance.

### **Specification**

5. The disclosure is objected to because of the following informalities:

Page 1, the priority statement must be amended to reflect the current status of all priority applications,

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

### **Double Patenting**

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 09/886,349. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a fusion protein which has the same amino acid sequence, sequence id no:10 in 09/597,796, and sequence id no:20 in 09/886,349.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application

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No. 10/359,460. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a fusion protein which has the same amino acid sequence, sequence id no:10 in 09/597,796, and sequence id no:26 in 10/359,460.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-4, 6, and 62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, and 6 of copending Application No. 09/886,349. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a fusion protein which has the same amino acid sequence, sequence id no:12 in 09/597,796, and sequence id no:16 in 09/886,349.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-4, 6, and 62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/359,460. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a fusion protein which has the same amino acid sequence, sequence id no:12 in 09/597,796, and sequence id no:2 in 10/359,460.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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11. Claims 1-4, 6, and 62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,544,522.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a polypeptide which has the same amino acid sequence, SEQ ID NO:12 in 09/597,796 and SEQ ID NO:2 in 6,544,522.

### **Claim Rejections - 35 USC § 112**

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 is drawn to "A composition comprising a fusion polypeptide comprising BCG and an amino acid sequence of MTB72F (SEQ ID NO:12)." It is unclear how one has a fusion polypeptide which comprises a whole bacterium and an amino acid sequence.

15. Claims 55 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 55 is dependent from to a cancelled claim, 16. Claim 61 depends from claim 55.

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16. Claims 6 and 56-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is drawn to a composition comprising a fusion polypeptide. The fusion polypeptide is encoded by a polynucleotide that hybridizes under stringent hybridization conditions to the complement of a polynucleotide "comprising" the nucleotide sequence of MTB72F (SEQ ID NO:11).

The encoding polynucleotide may be of undetermined length as long as it hybridizes with the complement of a polynucleotide "comprising" SEQ ID NO:11. The open language of the claim allows for the encoding polynucleotide to be of undetermined length with unknown encoding regions in addition to that which hybridizes to the complement of a polynucleotide, again of undetermined length, which "comprises" SEQ ID NO:11. There is no requirement for the polypeptide to be encoded by any known region. Therefore, the actual identity of the fusion polypeptide is unknown.

Claims 56-60 depend from claim 6, but do not correct the indefiniteness.

17. Claim 63 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a composition comprising BCG and a fusion polypeptide. The fusion polypeptide is encoded by a polynucleotide that hybridizes under stringent hybridization conditions to the complement of a polynucleotide comprising the nucleotide sequence of MTB72F (SEQ ID NO:11).

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The encoding polynucleotide may be of undetermined length as long as it hybridizes with the complement of a polynucleotide "comprising" SEQ ID NO:11. The open language of the claim allows for the encoding polynucleotide to be of undetermined length with unknown encoding regions in addition to that which hybridizes to the complement of a polynucleotide, again of undetermined length, which "comprises" SEQ ID NO:11. There is no requirement for the polypeptide to be encoded by any known region. Therefore, the actual identity of the fusion polypeptide is unknown.

18. Claims 7-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from rejected claims.

### **Conclusion**

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.



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21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

August 18, 2004